#7. 15AB

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* DARLA REID,	)	Civil Action No.: 13-0715
Plaintiff-Relator,	)	**FILED UNDER SEAL**
v.	)	**JURY TRIAL DEMANDED**
MED-FAST PHARMACY, INC.	)	
Defendant.	)	

SEALED COMPLAINT

Relator Darla Reid, by and through undersigned counsel and on behalf of the United States of America, hereby files the within complaint against defendant Med-Fast Pharmacy, Inc. ("Defendant"), averring as follows:

Introduction

1. This action pursuant to the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), seeks to recover damages and civil penalties on behalf of the United States arising out of Defendant making or causing to be made false claims for payment to the United States, its agents and intermediaries.

2. Ms. Reid came to know of Defendant's illegal scheme and practices while she was employed by Defendant in its mail order, over-the-counter and institutional pharmacy operations.

3. While so employed, Ms. Reid became aware of Defendant's scheme to submit or cause submission to the government of claims for reimbursement, and to make, use and/or cause to be made or used false records or statements material to

such reimbursement, related to Defendant's provision of pharmaceutical products knowingly packaged and provided by Defendant in violation of applicable law.

4. For example, while Ms. Reid worked for Defendant she was instructed to fabricate expiration dates, lot numbers and other required information in packaging and distributing pharmaceutical supplies, many of which were most likely furnished to beneficiaries of federally-funded healthcare programs.

5. These practices violated legal requirements upon which the United States government conditions reimbursement, such that every time Defendant, or customers to whom Defendant had implicitly signaled its compliance with such prerequisites by supplying the products, submitted or caused submission of claims for reimbursement with respect to the improperly-packaged drugs.

6. Defendant, by instructing its employees to fabricate required information on drug labels and to supply expired and improperly re-packaged medical supplies, further made, used or caused the making or use of false records material to the United States' decision to reimburse such claims.

7. Defendant knowingly committed these violations. For instance, on at least one occasion, supervisors and employees at Defendant's pharmacy intentionally concealed the evidence of these improper practices from an inspector from the U.S. Drug Enforcement Association (DEA). Moreover, not only did Defendant's supervisors instruct and condone the improper pharmacy practices, but Defendant's executives and officers recklessly and deliberately disregarded Ms. Reid's complaints of such practices.

8. Instead, Defendant retaliated against Ms. Reid by creating and permitting a hostile work environment after Ms. Reid began cooperating with the DEA and U.S. Food and Drug Administration (FDA) to investigate Defendant's improper practices and by terminating Ms. Reid's employment shortly after learning that she had reported Defendant's knowingly fraudulent behavior.

9. Based on these unlawful actions, as elaborated below, Defendant is liable for violating the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) and 3730(h).

Jurisdiction and Venue

10. This is a civil action on behalf of the United States and arising under the laws of the United States, specifically 31 U.S.C. §§ 3729 & 3730. Jurisdiction is therefore proper pursuant to 31 U.S.C. § 3732, which confers federal subject matter jurisdiction over FCA actions, 28 U.S.C. § 1331, regarding federal question jurisdiction, and 28 U.S.C. § 1345, because the United States is a plaintiff.

11. Upon information and belief, none of the substantive allegations or transactions described herein have been publicly disclosed, as defined in 31 U.S.C. § 3730(e)(4)(A).

12. To the extent that any such public disclosure has occurred, this action is not barred because Ms. Reid is an "original source" as defined in 31 U.S.C. § 3730(e)(4)(B). By virtue of her employment with Defendant, Ms. Reid has direct and independent knowledge of the FCA violations described herein, and on January 11, 2013 she voluntarily disclosed that information to the government, specifically the DEA, before filing the instant action.

13. Defendant can be found and transacts business in the Western District of Pennsylvania, and a substantial portion of Defendant's actions giving rise to this action took place therein. Venue is therefore proper pursuant to 31 U.S.C. § 3732(a).

The Parties

14. Relator Darla Reid is an adult individual who resides in New Brighton, Pennsylvania.

15. Defendant Med-Fast Pharmacy, Inc is a pharmacy services company with its headquarters in Aliquippa, Pennsylvania. Defendant maintains at least thirteen (13) corporate and retail locations in Pennsylvania, and Defendant also transacts with customers outside of Pennsylvania by providing pharmaceutical products through its mail order department

16. The pharmacy services Defendant provides include the distribution of pharmaceutical products to retail pharmacies, the operation of retail pharmacies, and providing medication and other pharmaceutical supplies to both mail order customers and patients in long-term care facilities.

The FDCA

17. The Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 352, prohibits "misbranding" drugs or pharmaceutical products.

18. This prohibition requires pharmacies such as Defendant to refrain from labeling medication or other pharmaceutical supplies with "misleading" information about the nature of the product. 21 U.S.C. § 352.

19. Expiration dating is one of the items that cannot be "misleading" pursuant to this FDCA provision. 21 C.F.R. §§ 201.17, 211.137.

20. The FDCA also requires that, where a National Drug Code (NDC) is required to be or is otherwise displayed on a label, the NDC must be correctly displayed in accordance with applicable regulations. 21 C.F.R. §§ 201.2, 207.35.

21. Further, the FDCA requires that pharmaceuticals not be "adulterated." 21 U.S.C. § 351.

22. As explained below, because Defendant received federal reimbursement through the Medicare and Medicaid programs, Defendant was at all relevant times obligated to comply, and certify its compliance, with the FDCA.

Medicare and Medicaid

23. Congress instituted the Medicare Program ("Medicare") in 1965 to pay for the costs of certain healthcare services provided to individuals of qualifying age or disability and to individuals suffering with end-stage renal disease ("Medicare beneficiaries"). 42 U.S.C. §§ 426, 426A.

24. Similarly, the Medicaid Program ("Medicaid") was enacted to extend, through combined federal and state funding, healthcare to certain groups in need including low-income families, individuals receiving Social Security benefits and "qualified severely impaired individuals." 42 U.S.C. §§ 1396a & 1396b.

25. The United States government, specifically the Department of Health and Human Services (HHS) through the Centers for Medicare and Medicaid Services (CMS), administers and supervises Medicare and Medicaid and is

responsible for reimbursement of services rendered to those programs' beneficiaries. *See, e.g.*, 42 U.S.C. §§ 1395b-9, 1396b.

26. Medicare Part A provides federal reimbursement for, *inter alia*, the cost of post-hospital nursing facility care. 42 U.S.C. § 1395c-1395i5.

27. Medicare Part B helps cover the cost of services rendered by healthcare providers, including costs of and outpatient care and of other medical services that are not covered by Medicare Part A. *Id.* §§ 1395j-1395w5.

28. Medicare Part D provides reimbursement for outpatient prescription medication and supplies provided to for patients who receive Medicare Part A and B benefits. *Id.* §§ 1395w101-1395w154.

29. Part D was added to Medicare by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub L. 108-173 (Dec. 8, 2003), *enacted at* 42 U.S.C. §§ 1395w-101 *et seq.*; it provides wide-reaching federal funding for covered prescription drugs and supplies. *See also* 42 C.F.R. § 423.506.

30. As of January 2006, Medicare began to provide outpatient prescription drug coverage through Part D based upon a reimbursement level set for each drug, for which Part D supplies direct payment to pharmacies as reimbursement for prescription drugs actually dispensed. *See* 42 U.S.C. § 1395w-102

31. Part D coverage is not provided within standard Medicare, and Part D beneficiaries must enroll in one of numerous Part D plans offered by private companies called "Plan Sponsors." 42 U.S.C. §§ 1302, 1395w-101 through 152, 1395hh.

32. Part D Plan Sponsors may contract directly with healthcare providers, including pharmacies such as Defendant, or they may contract with other entities called Pharmacy Benefits Managers, which provide administrative services and serve as intermediaries between Plan Sponsors and providers. 42 C.F.R. § 423.501.

33. When a pharmacy dispenses prescription drugs to a Part D beneficiary, the pharmacy must submit certain required data for each related prescription to either the Plan Sponsor or Pharmacy Benefits Manager, which then submits such data to the CMS. *See generally* 42 C.F.R. Part 423, "Medicare Part D Claims Data"; 42 C.F.R. § 423.322.

34. CMS then pays the Plan Sponsor or Pharmacy Benefits Manager according to the set rate for the specific pharmaceutical product(s) provided to Part D beneficiaries, and the intermediary in turn reimburses the pharmacy. *See id.*

35. In order to receive reimbursement from the government, through Medicare or Medicaid, a pharmacy must certify that it has complied with legal requirements governing labeling, including FDCA provisions requiring pharmacies to label pharmaceuticals with accurate expiration dates and lot numbers. *See* 42 C.F.R. § 423.153(c). *See also* 49 Pa. Code §§ 27.14, 27.18, 42 C.F.R. § 423.505(b)(15) (requiring Plan Sponsors to adhere to state law).

36. Part D further requires that pharmacies comply with FDCA regulations prohibiting misbranding of drugs, including the requirement of accurate expiration dates and lot numbers. *See* 21 U.S.C. §§ 331, 333; 21 C.F.R. §§ 201.17, 201.18 & 211.137.

37. Likewise, pursuant to Part D both pharmacies and Plan Sponsors must comply with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal Criminal law, the False Claims Act . . . and the anti-kickback statute." 42 C.F.R. § 423.505(h)(1).

38. Part D reimbursement is also expressly conditioned upon providers' certification that they have submitted "accurate, complete, and truthful" claims data to CMS. *Id.* § 423.505(k).

39. In addition, pursuant to the Patient Protection and Affordable Care Act of 2008, providers must now provide CMS with information regarding the units of each dosage form, strength and package size by the National Drug Code (NDC) for each covered outpatient medication dispensed to a Medicaid beneficiary. 42 U.S.C. § 1392r-8.

40. The NDC is an eleven-digit number that a manufacturer or labeler must, pursuant to the FDCA, assign to a specific pharmaceutical product at the time of packaging; the NDC identifies the product manufacturer, dose form and strength, and the package size unique to each product. *See* 21 C.F.R. § 210.25(c)(1).

Defendant Is Subject to Reporting and Certification Requirements

41. For instance, Defendant's long-term care department (also known as the "institutions department") fills prescriptions for patients in long-term care facilities, which typically contract with pharmacies like Defendant to provide the drugs and other pharmaceutical products needed by their patients.

42. Defendant also provides pharmacy services to the Commonwealth of Pennsylvania on a contractual basis through the Pennsylvania Medical Assistance Program, whereby Defendant agrees to provide pharmaceuticals to Pennsylvania Medicaid patients and the Pennsylvania Department of Public Welfare agrees to reimburse Defendant for those pharmaceuticals.

43. Upon information and belief, a number of patients in such institutions are beneficiaries of Medicare and Medicaid by virtue of factors such as their age, income level, infirmity or disability.

44. Defendant therefore provides prescription drugs for distribution to a significant number of patients who are beneficiaries of federally-funded healthcare programs, including Medicare Part D and Medicaid.

45. Consequently, Defendant has, upon information and belief, received substantial federal reimbursement for pharmaceutical supplies it provided, either directly or through its institutional customers, to beneficiaries of Medicare, Medicaid and other government-funded health insurance programs.

Ms. Reid's Experience while Employed by Defendant

A. Over-the-Counter Department

46. Ms. Reid began working for Defendant on or about March 5, 2012, at which time she was assigned to work in the over-the-counter department in Defendant's facility in Baden, Pennsylvania.

47. In this capacity, Ms. Reid was to visit all of Defendant's retail stores each month to not only review the stores' cleanliness and customer service but also to examine the products on the shelves to determine whether the stores were effectively removing expired products.

48. While she was performing theses site visits, Ms. Reid often observed expired products on the stores' shelves and expired diabetes test strips behind the pharmacists' counters.

49. The manager of Defendant's over-the-counter department, Linda Funari, trained Ms. Reid to place expired pharmaceutical products in a tote.

50. Defendant's pharmacists would then determine which expired products in the tote could be returned to the wholesaler and would send the remainder of expired pharmaceuticals in the tote to Defendant's long-term care department, to the attention of director of special projects Dave Barna.

51. Ms. Funari similarly instructed Ms. Reid to place all expired boxes of diabetes test strips in a bag, staple the bag shut, and attach to the bag a form listing the number of boxes of expired test strips, the brand, the quantity of test strips in each box and the expiration dates.

52. Ms. Funari further instructed Ms. Reid to send the bags of expired test strips to the attention of Mr. Barna in Defendant's mail order department.

53. After Ms. Reid, at her supervisor's instructions, thus removed expired pharmaceutical products and supplies from one of Defendant's stores, she frequently found the same expired products back on the shelves of the same store – and available to customers – when she reviewed that store the following month.

54. On information and belief, in particular based upon Defendant's practice of returning expired products to the shelves of its stores within a month of Ms. Reid pulling the same products as expired, some expired products removed from Defendant's retail pharmacies were distributed to patients in long-term care facilities and to mail order customers supplied by Defendant.

55. Also while working in Defendant's over-the-counter department, Ms. Reid engaged in some marketing activities, including outreach to present or potential customers of Defendant.

56. In the context of marketing Defendant's services, Ms. Reid mentioned to Defendant's President Doug Kaleugher that Ms. Reid's brother worked for Supportive Services, one of Defendant's customers that operates residential care facilities for individuals with mental and physical disabilities.

B. Long-Term Care Department

57. On or about November 9, 2012 Ms. Reid was transferred from the over-the-counter department to work as a pharmacy technician in Defendant's long-term care department.

58. Defendant's long-term care department was primarily responsible for filling prescriptions for patients in long-term care facilities.

59. Upon information and belief, many of those patients, by virtue of such factors as their age, the nature of their infirmity, their disabilities or their history of serving in the United States armed forces, were and are beneficiaries of federally-funded healthcare programs.

60. The manager of Defendant's long-term care department was Correna Pfeiffer, a pharmacist who supervised the entire department including approximately fifteen (15) pharmacy technicians and three (3) pharmacists.

61. Ms. Reid's primary responsibility in the long-term care department was to assist in filling prescriptions for patients in long-term care facilities.

62. When Ms. Reid began working as a pharmacy technician in the long-term care department, she did not have a pharmacy technician license, she had no pharmacy training and she had never previously worked with medications.

63. Although Ms. Reid repeatedly requested a written protocol for long-term care department policies, practices or procedures, and although such protocol must be maintained pursuant to Pennsylvania law, 49 Pa. Code § 27.12, Defendant never provided her with any such writing and Ms. Reid never saw any evidence that Defendant maintained written procedures for practices in its long-term care department.

64. Defendant did not formally train Ms. Reid to work as a pharmacy technician as required by Pennsylvania law. 49 Pa. Code § 27.12.

65. Rather, while working in the long-term care department Ms. Reid was trained only by Jillian Price, who was also a pharmacy technician.

66. From the time Ms. Reid began working in Defendant's long-term care department in 2012 through at least March 2013, all pharmacy technicians in that department were, like Ms. Reid, trained only by their co-workers and only as needed.

67. Defendant's long-term care department stored drugs and other pharmaceutical products in two different types of bottles on shelves.

68. Approximately half of the medication on the shelves in Defendant's long-term care department was stored in the bottles supplied by the manufacturers.

69. The other half of the drugs stored in Defendant's long-term care department was kept in orange bottles marked only with limited information necessary to identify the drug, such as its name and strength, without expiration dates, lot numbers, NDCs or other information required by law.

70. Prescriptions for patients in long-term care facilities served by Defendant were filled by placing drugs in "bubble cards," each of which contained a one-month supply of one dose of a particular drug.

71. One side of each bubble card contained a printed label listing the patient's name, the name and strength of the medication contained in the bubbles and directions for administering the drug, as well as an empty space in which pharmacy technicians in Defendant's pharmacies would write the drug's expiration date and lot number by hand.

72. When Ms. Reid worked in Defendant's long-term care department, she or another pharmacy technician was responsible for printing these labels as the first step in filling each prescription.

73. Once the labels were printed, another pharmacy technician would pull the prescribed drugs from the storage shelves, count the pills needed to fill the prescription and place them in another bottle if necessary, and then place the labels and bottles of drugs in shoe-box-size bins.

74. Each such bin usually contained labels and bottles of drugs for multiple patients in the same long-term care facility.

75. At times, when Ms. Reid received the bins containing the labels and bottles of drugs, the bottles contained only the drug's name and no other information or else were completely unmarked.

76. Thus, as observed by Ms. Reid while she was employed by Defendant, bottles of medication filled by technicians in Defendant's long-term care pharmacy often did not provide required information such as the drug's expiration date, lot number or NDC.

77. Pharmacist Paul Higginbotham directed Ms. Reid to identify the types of pills in the bottles using a website, by which she could match images of the pills with their names.

78. The website, however, did not and could not supply information required by law such as expiration date, lot number or NDC, which is provided by

the manufacturer and unavailable from the orange bottles in which Defendant stored approximately half of the medication in its long-term care department.

79. At times Ms. Reid had to fill the bottles of medication placed in bins in Defendant's long-term care department.

80. This required Ms. Reid to engage in "fishing" by going to the shelves containing the inventory of medications in Defendant's long-term care department and pulling from those shelves the drugs needed to fill each bubble card.

81. Ms. Reid would also fill prescriptions by placing the bottled medication into bubble cards, sealing the bubble cards, placing the labels on the bubble cards and writing in by hand on each label the expiration date and lot number of the medication along with her initials.

82. Once this process was complete, a pharmacist in Defendant's long-term care department would verify only that the bubble cards contained the correct drug, that there was only one pill in each bubble and that none of the pills were broken.

83. If the pharmacist discovered any mistake, a pharmacy technician such as Ms. Reid would create a new bubble card and place the flawed bubble card in a bin resembling a trash can.

84. The bin in which pharmacy technicians placed discarded, flawed bubble cards also contained drugs that, upon information and belief, had been returned to Defendant by long-term care facilities.

85. Once filled properly, all bubble cards produced in Defendant's long-term care department for patients in a particular long-term care facility were placed in a brown paper bag designated for that facility.

86. On or about November 20, 2012, Ms. Reid approached Defendant's vice president Gino Cordisco and expressed a number of concerns she had about workplace conditions, including possible improper dispensing and general practice issues Ms. Reid perceived in the pharmacy.

87. On that same date, Defendant transferred Ms. Reid from its long-term care department to its mail order department.

C. Mail Order Department

88. Defendant's mail order department fills prescriptions and provides prescription drugs and supplies via mail to diabetes patients.

89. Upon information and belief, many of the diabetes patients to whom such supplies are provided are beneficiaries of federally-funded healthcare programs, in particular Medicare Parts B and D, which cover costs to beneficiaries of diabetes supplies and services. *See generally* 42 U.S.C. §§ 1395j-1395w5, 1395w101-1395w154.

90. Ms. Reid's manager in the mail order department was Brittany Smith.

91. During the months Ms. Reid worked in Defendant's mail order department in 2012 and early 2013, Ms. Smith more than once instructed Ms. Reid to use expired drugs to fill mail order prescriptions, and Ms. Reid complied.

92. On one particular occasion in early 2013, Mr. Barna brought a box of the prescription drug Atenolol to the mail order department.

93. All of the Atenolol in the box expired three weeks from the date in early 2013 that Mr. Barna provided the box.

94. Defendant's manager Brittany Smith, over Ms. Reid's objection, insisted on keeping the box of Atenolol in the mail order department.

95. Subsequently, and after the Atenolol expired, Ms. Smith instructed Ms. Reid to use the expired Atenolol to fill mail order customers' prescriptions. Ms. Reid complied.

96. Defendant's mail order customers, who upon information and belief include many Medicare and Medicaid beneficiaries, thus on occasion received expired and otherwise mislabeled products and as a result claims for reimbursement of these products were submitted to the United States government.

97. The box Mr. Barna brought to the mail order department in early 2013 also contained other medication that, upon information and belief, was also short-dated and was provided to and distributed through pharmacies in Defendant's other departments.

98. Thus, upon information and belief, Defendant provided expired supplies to its other customers and thereby to federal healthcare beneficiaries, resulting in the submission of additional false claims for reimbursement to the United States, which by law does not reimburse for expired medications.

99. Defendant also similarly provided improperly-marked and unlawfully "misbranded" diabetes supplies that, upon information and belief, likewise resulted

in submission to the government of claims for reimbursement to which Defendant was not entitled.

100. For instance, Defendant's mail order department furnished to its customers diabetes supplies such as lancing devices and solutions.

101. Defendant obtained these supplies from prepackaged kits, which display expiration dates and identifying information such as lot numbers and NDCs, although the kits' separate components do not display such information.

102. Ms. Reid learned through conversation with her coworkers that the motivation for Defendant's practice of selling the components of diabetes supply kits separately was to make more money than Defendant could earn by selling the diabetes supply kits in their original packaging.

D. Defendant's Scheme to Fabricate Required Information

103. On Ms. Reid's first day in the long-term care department, Defendant's manager Pfeiffer instructed Ms. Reid to "rotate" bottles of medication stored on the department's shelves, specifically to move medication closest to expiring to the front and the newest medication to the back of the shelves.

104. In complying with her supervisor's request, Ms. Reid found a number of bottles of expired medication and many more that had expiration dates less than six months away. Defendant's employees commonly referred to the latter class of medication as "short-dated."

105. Ms. Reid was told to remove the expired and short-dated drugs from the shelves and place them in a box.

106. Although she did so, Ms. Reid only had time to "rotate" the drugs on a few of the many storage shelves throughout Defendant's long-term care department.

107. Despite having left many expired and short-dated medications on the shelves, Ms. Reid never saw anybody else "rotating" bottles after her first day in the long-term care department, when she discovered expired and short-dated medication on the few storage shelves she was able to examine.

108. Also while she was working in Defendant's long-term care department, Ms. Reid was instructed by her coworker Jillian Price to fabricate expiration dates supplied on the bubble cards, and that the date she chose had to be between one and three years after the date that the prescription was filled

109. Ms. Reid received no instruction or guidance at all with respect to lot numbers or NDCs.

110. Ms. Reid quickly learned from personal observation and through conversations with her coworkers that the pharmacy technicians in Defendant's long-term care department were making up the expiration dates and lot numbers that they wrote on patients' bubble cards.

111. When Ms. Reid questioned this practice, Ms. Price told her that it saved time and was "not a big deal."

112. Consistent with both her training and department-wide practice, when working in Defendant's long-term care department Ms. Reid created fictional lot numbers and expiration dates when she was completing labels on bubble cards.

113. For example, Ms. Reid at times wrote her phone number backwards and forwards, her social security number, her child's birthday and other random numbers in place of actual lot numbers.

114. Only expiration dates and lot numbers were provided for the bubble cards provided by Defendant's long-term care department; the bubble cards did not did not list NDCs, and they did not contain bar codes.

115. In addition, Ms. Reid did not and was not instructed to maintain a log of or otherwise track the prescriptions she filled, nor did she track the expiration dates, lot numbers, NDCs or any other data associated with those prescriptions.

116. Moreover, while she worked in Defendant's long-term care department in November 2012, Ms. Reid did not witness any of Defendant's employees, supervisors or managers tracking the prescriptions or associated data related to bubble cards provided by Defendant's long-term care department.

117. Whenever Ms. Reid had to "fish" for drugs, she frequently had to pull drugs from the poorly-marked orange bottles listing no expiration dates, lot numbers or NDCs and she would therefore have to simply invent the expiration dates and lot numbers that she placed on the bubble cards.

118. Upon information and belief, the other pharmacy technicians in Defendant's long-term care department likewise had to and did fabricate data, required by CMS, that they placed on the labels of medications disbursed to Defendant's long-term care customers.

119. Defendant also knowingly supplied expired drugs; as explained above, while Ms. Reid worked in Defendant's mail order department, Defendant's director of special projects Dave Barna often brought into the department boxes of medication that was short-dated and sometimes expired only two weeks from the date that Mr. Barna provided them.

120. Defendant then used short-dated drugs, such as those supplied by Mr. Barna, to fill prescriptions that were distributed by Defendant to patients in the long-term care facilities and to customers of Defendant's mail order pharmacy.

121. Upon information and belief, expired supplies were similarly used to fill patients' prescriptions and were distributed, *inter alia*, to patients in the long-term care facilities serviced by Defendant.

E. Defendant Knowingly Engaged in Unlawful Practices.

122. On November 10, 2012, which was Ms. Reid's second day working in Defendant's long-term care department, DEA Inspector Thomas Duda arrived unexpectedly at Defendant's premises.

123. In the presence of Ms. Reid, all of the employees in Defendant's long-term care department reacted frantically and began yelling "inspector, inspector!"

124. At the instruction of Defendant's manager Correna Pfeiffer, the employees immediately began to clear all unmarked orange bottles of drugs off of the storage shelves in Defendant's long-term care department.

125. The pharmacists, including Mr. Higginbotham and supervisor Pfeiffer, likewise concealed and/or rearranged items in their workspace in anticipation of the DEA inspection.

126. Ms. Reid, along with other employees including pharmacy technicians Derron Burd, Tiffany Burd, Tasha Koble and Kristin Stevenson, in the presence of pharmacist Paul Higginbotham and pharmacist-manager Correna Pfeiffer, removed the orange bottles of medication from the storage shelves and placed them in green totes approximately two feet long, one foot wide and one foot deep.

127. The orange bottles that the pharmacy technicians removed from the shelves of Defendant's long-term care department filled at least two-and-one-half of these capacious green totes.

128. Manager Pfeiffer and employee Burd devised and executed a plan to conceal the totes and deficiently-labeled bottles from DEA Inspector Duda by placing the totes in a vehicle used by Defendant's delivery driver.

129. After the medication was so concealed, Defendant's long-term care department employees verified expiration dates on the manufacturers' bottles of medication remaining on the shelves.

130. Ms. Reid found an expired bottle, removed it from the shelf and hid it under her arm, while another employee hid several bottles in drawers.

131. Once DEA Inspector Duda left Defendant's premises without incident, Ms. Reid witnessed an atmosphere of celebration shared by employees and supervisors of Defendant's long-term care department.

132. After this incident, on November 20, 2012, Ms. Reid approached Defendant's Vice President Gino Cordisco to voice a number of concerns she had regarding practices in Defendant's pharmacies, including that employees including

Ms. Reid were instructed to make up lot numbers and expiration dates, and Defendant's apparent policy of supplying patients with pharmaceutical products that were expired, would soon expire or might be improperly repackaged.

133. Mr. Cordisco dismissed Ms. Reid's concerns, and neither he nor anyone else in Defendant's management investigated, addressed or tried to correct the problems Ms. Reid brought to Mr. Cordisco's attention.

134. However, as noted above Defendant transferred Ms. Reid out of the long-term care department to its mail order department on the same day she complained to Mr. Cordisco.

135. Defendant also asked Ms. Reid, after she brought her concerns to management's attention on November 20, 2012, to sign forms certifying that she had undergone proper and necessary training to work as a pharmacy technician.

136. Ms. Reid had not undergone the training referenced in the forms, and she refused to sign them.

137. Upon information and belief, none of Ms. Reid's co-workers was ever properly trained or asked to sign these forms.

138. On January 10, 2013, Ms. Reid tried to circumvent Mr. Cordisco's and her supervisors' disregard of her reports of Defendant unlawfully fabricating lot numbers and expiration dates and distributing expired and repackaged drugs, and she brought those issues to the attention of Defendant's President Doug Kaleugher.

139. Like Mr. Cordisco, Mr. Kaleugher dismissed Ms. Reid's concerns.

140. On January 11, 2013, Ms. Reid disclosed Defendant's fraudulent practices to DEA Agent Lewis Colosimo.

141. Subsequently, Ms. Reid's concerns were also divulged to U.S. Food and Drug Administration ("FDA") special agent Michael Kurisky.

142. Ms. Reid thereafter met in person with Agent Colosimo and Special Agent Kurisky, and since that time she has cooperated extensively with the DEA in its investigation of Defendant's unlawful activities, including a number of phone calls, emails and text message exchanges frequently since January 2013.

143. After Ms. Reid raised her concerns about Defendant's fraudulent practice with Defendant's President Kaleugher and then with Agent Cordisco and Special Agent Kurisky, and externally with the DEA and FDA, the environment for Ms. Reid at Defendant's premises became increasingly unbearable.

144. Specifically, as of January 20, 2013 Ms. Reid was no longer allowed to take the breaks afforded to other employees who acquiesced in Defendant's fraudulent scheme, Defendant began inundating Ms. Reid's personnel file with manufactured complaints about her conduct and her employment status was threatened on numerous occasions by Mr. Kaleugher.

145. As a result of this hostile work environment to which Defendant subjected Ms. Reid after her reports of Defendant's fraudulent activities, Ms. Reid struggled with anxiety and depression and began to suffer from panic attacks.

146. On March 1, 2013, Ms. Reid was sorting prepackaged medications and realized after she removed the medication from its packaging and placed it on her sorting tray that the package contained two different types of medication.

147. At the same time, Ms. Smith came to instruct Ms. Reid to report to Mr. Kaleugher's office.

148. In doing so, Ms. Smith observed that Ms. Reid had two different types of medication on her sorting tray and immediately began lambasting Ms. Reid for an apparent violation of protocol.

149. Ms. Reid tried to explain that she did not deliberately place two types of medication on her tray and that the medication had come prepackaged in that manner.

150. Yet Ms. Smith refused to listen to this explanation and reiterated the demand that Ms. Reid report to Mr. Kaleugher's office.

151. Ms. Reid did so, and when Ms. Reid reported to Mr. Kaleugher's office he told her that he had received a phone call from a representative of Defendant's customer Supportive Services claiming that one of Defendant's employees, "named Darla," had informed a different Supportive Services employee that Defendant was supplying Supportive Services with expired drugs.

152. Mr. Kaleugher immediately terminated Ms. Reid's employment, telling her to "get the hell off" of his property and that he did not ever want to see her face again.

153. Defendant has since taken the *post hoc* position that it terminated Ms. Reid because, in addition to allegedly lying to Supportive Services about Defendant's fraudulent activities, Ms. Smith observed two different types of medications at the same time on Ms. Reid's sorting tray.

154. This after-the-fact rationale is plainly pretext in light of Defendant's differing articulations of it over time and in particular of Mr. Kaleugher's apparent reliance only on Supportive Services' claims against Ms. Reid in deciding to terminate her employment.

F. False Claims for Medicaid and Medicare Payments

155. Defendant must expressly certify, in order to be eligible for reimbursement pursuant to Medicare and Medicaid, its compliance with applicable federal laws and regulations, CMS instructions and state law. *See* 42 C.F.R. §§ 423.153(c), 423.505(i)(3)(v).

156. For this reason, each claim for reimbursement that Defendant submits or causes to be submitted to Medicare or Medicaid is premised, either directly or indirectly, upon Defendant's compliance with applicable federal laws and regulations, CMS instructions and state law.

157. A pharmacy such as Defendant violates the FCA by submitting, or by causing submission of, a claim to Medicare or Medicaid seeking reimbursement with respect to a pharmaceutical product labeled with an incorrect expiration date and/or lot number, because applicable Medicare and Medicaid statutes and regulations preclude reimbursement for such product. *See* 31 U.S.C. § 3729(a)(1)(A).

158. The same is true with respect to improperly repackaged medication, a pharmacy's distribution of which violates the FDCA as explained above. *Id.*

159. Such a false claim would also result due to Defendant's making and use of labels containing inaccurate expiration dates and lot numbers, both of which must, pursuant to applicable state and federal law, be accurately identified on the pharmaceutical supplies. *Id.* § 3729(a)(1)(B).

160. Thus, Defendant violated the FCA by submitting and causing submission to Medicare and Medicaid claims for reimbursement for improperly labeled and repackaged supplies that misrepresent the expiration date, lot number, NDC and/or nature of the product supplied.

161. Defendant, by submitting and/or causing to be submitted to the government claims for reimbursement, falsely certified its compliance with applicable law, cited above,

162. For instance, Defendant's fraudulent practices violate laws requiring that drug labels include proper expiration dates, lot numbers and NDCs.

163. Defendant also violated relevant federal law, cited above, prohibiting it from re-packaging supplies, including those that are expired or otherwise defective.

164. All of the claims for reimbursement Defendant has submitted, or caused to be submitted, to Medicare and Medicaid are false because they are tainted by Defendant's failure to comply with applicable law.

165. Defendant's fraud is material because, if the United States were aware of Defendant's practices of unlawfully labeling, repackaging and distributing

various pharmaceutical supplies, the government would not have authorized or issued reimbursement.

166. In addition, by fabricating expiration dates and lot numbers and writing the same on labels of medications supplied to its customers, Defendant made and used false statements that were, because they were misleading as to Defendant's failure to comply with applicable law, material to the government's decision to issue payment on claims associated with such medications.

Count I:
31 U.S.C. § 3729(a)(1)(A)

167. Relator Darla Reid hereby incorporates by reference the allegations made in the foregoing paragraphs 1 through 166 of this complaint.

168. The FCA imposes liability upon "any person who [ ] knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States government. 31 U.S.C. § 3729(a)(1)(A).

169. Through the acts described above, Defendant and its agents and employees, while acting within the course and scope of such agency and employment, knowingly presented and caused to be presented to the United States false claims for reimbursement relating to pharmaceutical services and products provided to beneficiaries of Medicare and Medicaid.

170. Each and every claim that Defendant submitted or caused to be submitted to the federal government from at least May 2012 and continuing through at least March 2013 is false because, as detailed above, Defendant violated

yet falsely certified its compliance with the legal prerequisites for obtaining Medicaid and Medicare reimbursement.

Count II:
31 U.S.C. § 3729(a)(1)(B)

171. Relator Darla Reid hereby incorporates by reference the foregoing paragraphs 1 through 170 of the within complaint as if fully set forth herein.

172. The False Claims Act prohibits knowingly making, using or causing to be made or used any false record or statement material to the United States' decision to issue reimbursement of a claim for payment. 31 U.S.C. § 3729(a)(1)(B).

173. Through the acts described above, from at least March 2012 through at least March 2013, Defendant and its agents and employees, while acting in the course and scope of such agency and employment, knowingly made, used and/or caused to be made and used false records or statements material to the government's decision to pay or approve claims with respect to which Defendants were not entitled to reimbursement under applicable Medicare and Medicaid laws.

174. The United States at all relevant times is and was unaware that the records, statements, and claims that Defendant, its agents and employees submit, or cause to be submitted, are false and fraudulent.

175. As a result, the United States has approved and paid, and continues to approve and pay, claims that it would not otherwise approve or pay.

176. By reason of these payments and approvals, the United States has been and continues to be damaged in an amount yet to be determined.

Count III:
31 U.S.C. § 3730(h)

177. Relator Darla Reid hereby incorporates by reference the foregoing paragraphs 1 through 176 of this complaint as if fully set forth herein.

178. The FCA entitles employees "all relief necessary to make that employee . . . whole" if she is terminated "or in any other manner discriminated against in the terms and condition of employment because of lawful acts done by the employee . . . to stop one or more violations of" the FCA. 31 U.S.C. § 3730(h)(1).

179. An employee so wronged may also be reinstated with equal status and may recover double back pay with interest "and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees." *Id.* § 3730(h)(2).

180. Ms. Reid engaged in protected activity by, *inter alia*, specifically reporting Defendant's fraudulent activities to Defendant's Vice President and President, the DEA and the FDA.

181. Defendant, and in particular its President, Mr. Kaleugher to whom Ms. Reid reported these issues directly, knew that Ms. Reid engaged in the above-described protected activity.

182. After Ms. Reid began reporting her concerns about the fraud, Defendant subjected Ms. Reid to a hostile work environment due to her protected activity; this discrimination included but was not limited to disparate work conditions not imposed upon employees who acquiesced in Defendant's frauds,

harassment, increased discipline and reports thereof, and threats by Mr. Kaleugher to Ms. Reid's employment.

183. Moreover, Mr. Kaleugher discharged Ms. Reid within hours of being advised that Ms. Reid had reported Defendant's fraudulent scheme to a third party, and at the time he terminated Ms. Reid Mr. Kaleugher specifically mentioned and objected to her report of the fraud.

184. Because of Defendant's unlawful retaliation against her, Ms. Reid has suffered a loss of employment opportunities and earnings and a loss of future earnings and earning capacity, and Ms. Reid has suffered and continues to suffer non-monetary damages including but not limited to emotional and physical distress, humiliation, embarrassment, loss of esteem and loss of enjoyment of life.

WHEREFORE, relator Darla Reid respectfully requests that judgment be entered against Defendant, ordering that:

(a) Defendant cease from violating the False Claims Act, specifically 31 U.S.C. §§ 3729(a)(1)(A) & (B) and 3730(h);

(b) Defendant pay an amount equal to three times the amount of damages the United States has sustained because of Defendant's fraudulent actions, plus a civil penalty against Defendant of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

(c) Ms. Reid be awarded the maximum amount of damages allowed pursuant to 31 U.S.C. § 3730(h);

(d) Ms. Reid be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(h);

(e) The United States and Ms. Reid be granted such other relief as the Court deems just and proper.

Further, Ms. Reid respectfully requests, on her own behalf, that judgment be entered in her favor and against Defendant, granting the following relief:

(a) An award of back pay with prejudgment interest;

(b) An award of two times the amount of back pay and interest on two times the amount of back pay pursuant to 31 U.S.C. § 3730(h)(2);

(c) An award of front pay in lieu of reinstatement;

(d) An award of general damages to compensate Ms. Reid for the mental and emotional distress caused by Defendant's misconduct;

(e) An award of punitive damages to deter and punish Defendant;

(f) An award of attorneys' fees and costs pursuant to 31 U.S.C. § 3730(h)(2); and

(g) An award of such other and further relief as this Court deems just and proper.

Demand for Jury Trial

Pursuant to Federal Rule of Civil Procedure 38, relator Darla Reid hereby demands a trial by jury.

Respectfully submitted,

BURNS WHITE LLC

By: */s/ Stephen S. Stallings*

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to Federal Rule of Civil Procedure 4(b)(4) and 31 U.S.C. § 3730(b)(2), a copy of the foregoing Sealed Complaint along with a written disclosure of substantially all evidence supporting the averments therein has been served via certified first-class, postage prepaid United States mail upon the following:

The Honorable David J. Hickton
United States Attorney for the Western District of Pennsylvania
c/o Michael A. Comber
Civil Division Chief
United States Attorney's Office
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/s/ Stephen S. Stallings
Stephen S. Stallings, Esq.